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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/736,801	12/16/2003	Bert Klebl	DEAV2002/0089 US NP	4154
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ANDREA Q. RYAN SANOFI-AVENTIS U.S. LLC 1041 ROUTE 202-206 MAIL CODE: D303A BRIDGEWATER, NJ 08807			EXAMINER HAMA, JOANNE	
			ART UNIT 1632	PAPER NUMBER
			NOTIFICATION DATE 01/04/2008	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPatent.E-Filing@sanofi-aventis.com
andrea.ryan@sanofi-aventis.com

Office Action Summary

Application No.

10/736,801

Applicant(s)

KLEBL ET AL.

Examiner

Joanne Hama, Ph.D.

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5-7,9,10,13-15,17,18,20,21 and 23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5-7,9,10,13-15,17,18,20,21 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Applicant filed a response to the Non-Final Action of April 10, 2007 on October 3, 2007.

Claims 2-4, 8, 11, 12, 16, 19, 22 are cancelled. Claims 1, 5, 9, 14, 17, 18, 20, 21 are amended.

Claims 1, 5-7, 9, 10, 13-15, 17, 18, 20, 21, 23 are under consideration.

It is noted that Applicant has not included claim 23 in the claims amended October 3, 2007 (see claims filed December 16, 2003, also Office Action, April 10, 2007, page 2). In the interest of compact prosecution, the Examiner will respond to Applicant's amendment in the following Office Action. Applicant is reminded that claim amendments must include a complete listing of all claims ever presented in the application, or risk non-entry of amendments (37 CFR 1.121).

Claim Objections

Claim 23 is objected under 37 CFR 1.75 as being a substantial duplicate of claim 9.

When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Withdrawn Rejections

35 U.S.C. § 101

Applicant's arguments, see page 5 of Applicant's response, filed October 3, 2007, with respect to the rejection of claims 17 and 18 have been fully considered and are persuasive.

Applicant has amended the claims such that they are not drawn to non-statutory subject matter. The rejection of claims 17 and 18 has been withdrawn.

Applicant's arguments, see amendment to the claims, filed October 3, 2007, with respect to claims 1, 3-15, 17, 18, 20, 21, 23 have been fully considered and are persuasive. Applicant has amended the claims such that the claims are drawn to yeast and no longer encompass multicellular organisms, which raised issues of specific and substantial utility. The rejection of claims 1, 5-7, 9, 10, 13-15, 17, 18, 21, 23 has been withdrawn. It is noted that the rejection of claims 3, 4, 8, 11, 12 is withdrawn as the claims have been cancelled.

35 U.S.C. § 112, 1st parag., New Matter

Applicant's arguments, see page 5 of Applicant's response, filed October 3, 2007, with respect to the rejection of claims 1, 3-15, 17, 18, 20, 21, 23 have been fully considered and are persuasive. Applicant indicates that the claims are directed to yeast and not to multicellular organisms. The rejection of claims 1, 5-7, 9, 10, 13-15, 17, 18, 21, 23 has been withdrawn. It is noted that the rejection of claims 3, 4, 8, 11, 12 is withdrawn as the claims have been cancelled.

35 U.S.C. § 112, 1st parag., Enablement

Applicant's arguments, see page 6 of Applicant's response, filed October 3, 2007, with respect to the rejection of claims 1, 3-15, 17, 18, 20, 21, 23 have been fully considered and are persuasive. Applicant indicates that the claims have been amended and are now drawn to yeast. The rejection of claims 1, 5-7, 9, 10, 13-15, 17, 18, 21, 23 has been withdrawn. It is noted that the rejection of claims 3, 4, 8, 11, 12 is withdrawn as the claims have been cancelled.

New/Maintained Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 5-7, 9, 10, 13-15, 17, 20, 21, 23 remain rejected in modified form under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant's arguments, see page 6 of Applicant's response, filed October 3, 2007, with respect to the rejections of claims 1, 3-17, 20, 21 have been fully considered and are persuasive in part.

With regard to the rejection as it applied to claim 11 for lacking clarity for what is meant by "phenotyping," Applicant indicates that claim 11 has been cancelled. The rejection of claim 11 is withdrawn as the claim is cancelled.

With regard to the use of the phrase, "modified expression," in claim 5, Applicant indicates that claim 5 has been amended such that "modified expression" refers to the expression in step a) of claim 1. The amendment is persuasive and thus, the rejection of claim 5 is withdrawn.

With regard to the rejection of claim 12 for lacking clarity as to why an artisan would reduce gene expression in the control organism, Applicant has cancelled claim 12. The rejection of claim 12 is withdrawn as the claim is cancelled.

It is noted that the rejections of claims 3, 4, 8, 11, 12 is withdrawn as the claims are cancelled.

With regard to the metes and bounds of the phrase, "perceptible from the outside," as recited in claim 1, Applicant indicates that the phrase refers to any modification or alteration of the yeast organism that can be measured on or outside of the modified organism and distinguishable from a wild-type unmodified yeast. Applicant indicates that on page 7, lines 13-17, the specification sets forth that analysis can "in principle include any modifications of the mRNA or protein steady state (transcription, translation, stabilization, etc.) and thus may also be carried out by protein profiling as well as the aid [of] [sic] [lacuna] protein assays." As such, "physical" (e.g. size, shape, growth, or rate of cell division, see page 1, lines 33-38) and "non-physical attributes" such as secreted proteins are encompassed by the specification and the term "perceptible from the outside" of the yeast organism. In response, Applicant's response does not clarify the metes and bounds of the claimed invention. While Applicant has clarified what is encompassed by a "perceptible" phenotype, wherein the term encompasses characteristics that can be detected by the naked eye and by an instrument (e.g. a tool that detects secretion of growth factor from a cell or microarray results that detect changes in gene expression), Applicant's response now raises the question of how step a) of claim 1 is carried out. In step a) of claim 1, an artisan needs to select yeast that comprise a transgene which does not produce a detectable change of the phenotype which is perceptible from the outside of the yeast. However, all yeast comprising a transgene will produce a detectable change in their phenotype, as detection of phenotype, according to Applicant's response, includes changes in gene expression that compensate for the changes caused by the transgene (see specification, page 2, line 38 to page 3,

line 8). As such, given the metes and bounds of what is encompassed by “phenotype” it is unclear how an artisan would arrive at any yeast that have no change in phenotype following introduction of a foreign gene into the yeast. As such, claim 1 and its dependent claims remain rejected.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 9, 10, 17, 18, 20, 21, 23 remain rejected under 35 U.S.C. 102(b) as being anticipated by Chattopadhyay et al., 2000, Journal of Bacteriology, 182: 6418-6423, for reasons of record, April 10, 2007.

Applicant's arguments filed October 3, 2007 have been fully considered but they are not persuasive.

Applicant indicates that claim 1 has been amended such that the heterologous expression of at least one protein or protein fragment occurs as a result of introducing a foreign gene into the yeast organism. Support can be found in the amendment of the instant specification, page 4, line 27. In response, this is not persuasive. The yeast used in Chattopadhyay et al.'s experiments are *btn1* knockout yeast, wherein the knockout was made by homologous recombination (see Pearce and Sherman, 1997, Yeast, 13: 691-697; Figure 1). The recombination construct contains a HIS3

reporter gene, wherein when HIS3 is expressed by the yeast, the yeast do not exhibit a detectable change of their phenotype perceptible from the outside of the yeast.

It is noted that while a 112, 2nd rejection has been written above, the Examiner maintains the rejection. It is understood from a strict reading of the specification that the yeast selected in step a) of claim 1 are yeast that have no readily apparent phenotype. Chattopadhyay et al. is readable on the claimed invention since Chattopadhyay et al. teach that btn1 knockout yeast have no readily apparent phenotype and a phenotype was detected following disruption of btn2 and hsp30 in btn1 disrupted yeast.

Thus, the rejection remains.

It is noted that the rejection of claim 5 is withdrawn as nothing in Pearce and Sherman, 1997, indicates that the His gene was driven by an inducible promoter.

The rejection of claims 3, 4, 8, 11 is withdrawn as the claims are cancelled.

Conclusion

No claims allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is 571-272-2911. The examiner can normally be reached Monday through Thursday and alternate Fridays from 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Joanne Hama
Art Unit 1632

/Anne Marie S. Wehbe/
Primary Examiner, A.U. 1633